

October 21, 2011

VIA ELECTRONIC FILING - http://www.regulations.gov

The Honorable Kathleen Sebelius Secretary, Department of Health and Human Services Room 445-G, Hubert H. Humphrey Building 200 Independence Avenue, SW Washington, DC 20201

Re: CMS-9982-P; Comments regarding the Proposed Rule on the Summary of Benefits and Coverage and the Uniform Glossary

Dear Secretary Sebelius:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to comment on the proposed rule on the Summary of Benefits and Coverage and the Uniform Glossary (CMS-9982-P) as provided for under the Affordable Care Act (ACA). PhRMA is a voluntary, non-profit organization representing the nation's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives.

The proposed rule implements a new provision promulgated by the ACA, specifically, the addition of section 2715 to the Public Health Service Act. Section 2715 directs the Internal Revenue Service, The Department of Labor and The Department of Health and Human Services (HHS) to "develop standards for use by a group health plan and a health insurance issuer in compiling and providing a summary of benefits and coverage (SBCs) that accurately describes the benefits and coverage under the applicable plan or coverage."

PhRMA supports efforts to promote consumer access to clear and complete information about plan benefits and coverage. Easy access to information of this kind is necessary in order for beneficiaries to make informed decisions about their healthcare coverage. Although the proposed rule adopts recommendations by the National Association of Insurance Commissioners (NAIC) on the elements for inclusion in an SBC, we believe it fails to include sufficient clarity regarding the information related to prescription drug coverage provided by Qualified Health Plans (QHPs).

Prescription medicines and their coverage are a critical factor that many beneficiaries take into consideration when choosing a healthcare plan. The proposed rule requires SBCs to include uniform definitions on coverage and medical terms and a brief description of coverage, including coverage examples and benefit scenarios. Since prescription medicines are often an

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integral component in treatment plans and pharmacy benefits are often subject to separate requirements, we urge HHS to require QHPs to provide accessible information on prescription drug coverage.

While we recognize that it is not practical to provide all necessary information in an SBC, we believe the proposed rule should provide guidance to assure appropriate access to supplemental information regarding prescription drug coverage. The proposed rule's requirement that the SBC contain an internet link where an individual can "find more information about the prescription coverage" is insufficient to assure that consumers have the information they need and could leave consumers to navigate complex websites to find complete formulary information. In addition, formulary documents can be overwhelming and difficult to search, leaving patients unsure about limitations on plan coverage and how much certain medications will cost. We believe additional guidance is important to assure that formulary documents available at the link are complete and in a format that promotes easy comparisons across plans. Such additional information provided to consumers should, at a minimum, meet requirements similar to those set forth in Chapter 3 Section 60.5 of the CMS Prescription Drug Benefit Manual on Formulary Notices and include, but not be limited to: a summary of what medicines are covered by the OHP, including co-pay and out-of-pocket cost information; and any step therapy, prior authorization or quantity limit that may apply to covered medicines (and the process to request an exception to such procedures). Without such information, we believe QHPs will not have the necessary guidance to ensure SBCs are a useful tool for consumers in making informed choices pertinent to their healthcare.

We appreciate your consideration of our comments. Please feel free to contact us with any questions.

Sincerely,

Jennifer M. Bryant